laboratories, the request form is separated from the specimen. Unfortunately, once an error has occurred there is often no opportunity to detect deviation from the ideal rapid passage through the Request-Test-Report cycle or to implement a corrective action to rectify this deviation.

To try to overcome this, a variety of approaches have been taken that have included a change of lid colour of specimen containers to indicate urgency, but this colour change has removed other critical information regarding the nature of the container and the anti-coagulant/preservative that is in the container. Containers use internationally recognised lid colours to indicate the anticoagulant inside and therefore the suitability of the sample inside the container for different specific tests. Hence, changing the colour of the lid is generally not preferred. Also, the lid of the container is often removed for specimen processing, and therefore any marker of urgency is lost from the sample if the urgent marker is only on the lid. A variety of other styles of markers have also been attempted, but these are applied manually part way through the Request-Test-Report cycle. The problems encountered with this approach are that again human error means that they may fail to be applied (omitted), are unreliably applied, and/or incorrectly applied, they may become dislodged, and, if they have been applied to the specimen container lid, they are deliberately removed from the sample during testing for many specimens/tests.

Previous attempts to use the specimen container as a vehicle to inform laboratory processing have failed due to a number of significant technical difficulties .

It should be appreciated that the walls of most specimen containers for laboratory testing are transparent and generally made of plastic or, less commonly, glass. To allow both visual inspection of the contents (eg volume of sample, visual inspection of sample for analytical interfering aspects of the sample such as haemolysis or lipaemia) and, in some instances for analysis to be performed, it is essential that the walls of the container are visually, and often, spectrophotometrically colourless and transparent; and that standard specimen container labels are not circumferential.

Attempts to use specimen containers made from coloured plastics or glass have failed due to spectral interferences with visual inspection and/or laboratory analysis. Attempts to use circumferential standard labels have failed due to the inability to inspect or analyse the sample. Attempts to use coloured bar-coded laboratory numbers have failed because they cannot be seen once the samples are placed onto analysers or in specimen racks. Attempts to coat the containers or contents with a coloured dye have failed due to chemical interferences with the sample, container contents or analytical test methods.

Yet another approach has been to photocopy each urgent request form to try to alert staff that one of the many samples they are handling must be processed urgently. This is expensive, inefficient, ineffective, and unreliable.

The consequence of these failings is that everyday in every laboratory in the world some urgent samples are not processed urgently and consequently have a significantly delayed turn around time. For some patients, care is compromised and patients can and do die or suffer a major adverse event. For some patients, there is a significant delay within the healthcare system and this has a personal cost to the patient and a huge financial cost to the healthcare system.

One approach to address problems with laboratory turn around times has been to implement laboratory automation. This often incurs a substantial capital investment and is not appropriate for all laboratories. While laboratory automation can assist with a global improvement in turn around times, it only addresses a relatively small portion of the entire Request-Test-Report cycle. Additionally, current laboratory automation systems rely on a manual or human bypass to deal with urgent samples. This manual approach is accompanied by all of the failures suggested above. Another approach to address problems with laboratory turn around times has been to introduce Point of Care Testing or Near Patient Testing. There is certainly a role for this within the healthcare system. However, at this point in time, systems are too slow, too expensive,

and too cumbersome to provide an effective solution if a number of tests are required when compared to an on-site laboratory using high throughput automated laboratory instruments. It is not practical or cost-effective for doctors and nurses near the patient to use 45-60 minutes of their time, a number of different small instruments, a number of different test consumables (e.g. cartridges) and a number of different patient sample types to obtain the same (or often less) information than an on-site laboratory can rapidly provide. An onsite laboratory can provide more comprehensive information (more test parameters/results), in less time, at less cost, and without using the time and resources of healthcare staff who are better utilised caring for sick patients (e.g. doctors and nurses in the Emergency Department).

In 2003, the Australian Council on Healthcare Standards (ACHS) published a report titled "Determining the Potential to Improve Quality of Care 4th ed - ACHS Clinical Indicator Results for Australia and New Zealand 1998-2002". Over a five year period, data was collected from between 14 – 25 hospitals with on-site laboratories. Data was obtained from all States in Australia and from New Zealand and included public and private healthcare facilities, large and small laboratories, metropolitan and rural laboratories.

This report highlighted major deficiencies in laboratory turn around times for urgent tests. Conservatively, this report demonstrated that on-site laboratories failed to deliver results within an acceptable turn around time in 5-20% of urgent cases. The mean failure rate for a request for some tests was 33% and, in some States of Australia, 60% of urgent specimens failed to have results available within a clinically appropriate time frame.

Inquiries with laboratories in Australia and Europe confirmed that the fastest 30% of urgent samples are tested and generally completed in clinically appropriate time frames. However, the slowest 30% can take more than 8 times longer. This then confirms the ACHS data and reflects on the inadequacies of the current systems in all laboratories in reliably delivering results for urgent samples within a clinically appropriate turn around time for

an acceptably high percentage of samples.

The ACHS data also highlights that there are real ceilings of capability utilising the current strategies. The data over the five year period generally shows fluctuations around common values rather than progressive and continued improvement. Depending on the specific tests, the current systems appear to be incapable of reliably delivering results for urgent specimens within clinically appropriate time frames for more than 79-92% of samples. A failure rate of 8-21% or more is considered to be not acceptable in a high quality healthcare system.

The following is ACHS data for urgent test specimens (percent of urgent specimens having results available within a specified clinically appropriate turn around time target). The mean is the mean percent of urgent specimens having results available within the specified turn around time target for all laboratories and the 80th percentile is the percent of urgent specimens having results available within the specified turn around time target for the best performing 80% of laboratories (i.e. the worst 20% of laboratories are excluded) (abbreviations K = plasma potassium, Hb = Haemoglobin) :

Year	K+ (normal hours)		K+ (out of hours)		Hb (normal hours)		Hb (out of hours)	
	Mean	80th percentile	Mean	80th percentile	Mean	80th percentile	Mean	80th percentile
1998	58.4%	73.5%	53.3%	80.1%	81.7%	92.1%	83.1%	91.6%
1999	64.0%	84.1%	71.9%	90.9%	88.1%	92.1%	80.8%	91.7%
2000	66.1%	79.5%	76.2%	84.3%	89.0%	93.2%	87.2%	90.6%
2001	61.1%	80.5%	71.8%	85.9%	88.0%	92.2%	87.2%	90.6%
2002	66.5%	78.7%	74.4%	85.9%	84.8%	91.7%	80.3%	91.2%

Indeed, the ACHS report states that the causes of variations and delays in turn around time need to be determined and that "those causes that are system related could be the object of a quality improvement

program to redesign the pathology processes". The ACHS report uses the data within the report to demonstrate that, because the failure rates are so high, improvements in the process that deliver gains could benefit up to 10 000 patients within each of their patient sample sets containing approximately 80 000 patients in each of their report categories.

The United States Institute of Medicine of the National Academies has produced a number of reports in recent years highlighting the urgent need to address significant issues in relation to healthcare and quality. There are also two Institute of Medicine (IOM) reports to address critical issues of inadequate safety and quality in the American Health Care System, "To Err is Human: Building a Safer Health System" (2003) and "Crossing the Quality Chasm: A New Health System for the 21st Century" (2001).

Indeed, "Crossing the Quality Chasm: A New Health System for the 21st Century" (2001) highlights that Six aims for Healthcare in the 21st Century are:

- Safe
- Patient Centred
- Efficient

indicator bands will expedite the testing process when no accompanying paperwork has been received or if requested tests are ordered electronically.

Further, the utilisation of specimen containers with incorporated indicator bands will overcome the many technical difficulties previously encountered with failed attempts to utilise the specimen container as a vehicle to inform laboratory processing.

EXAMPLE

A small pilot trial using sample containers with an incorporated priority indicator, as shown in FIG. 1A, was used on a small scale in an Emergency Department. The use of the specimen containers demonstrated a significant reduction in the number of samples that failed to have results for urgent specimens from an Emergency Department available within the specified turn around time targets. The results were as follows:

There was a 53% reduction in the failure rate (reduced from 16.5% to 7.7%) by using specimen containers with an incorporated priority indicator. This study only looked at the "within laboratory" component of testing (i.e. registration of the request onto the Laboratory Information System after receipt of the sample in the laboratory until result availability for clinicians).

It should also be appreciated that various other changes and modifications may be made without departing from the spirit or scope of the invention.